Art Unit: ***

CLMPTO

03/10/06

FRP

06/13/06

(Twice amended) A method of decreasing a risk of mortality caused by congestive heart failure in a patient in need of such decrease, said method comprising: administering to said patient first dosages at least daily for a period of from 7 to 28 days, said first dosages each comprising carvedilol,

then administering to said patient second dosages at least daily for a period of from 7 to 28 days, said second dosages each containing carvedilol, and

then administering to said patient third dosages daily for a maintenance period to decrease a risk of mortality caused by conqestive heart failure, said third dosages each comprising carvedilol, said maintenance period is greater than six months, and said third dosages each comprising a daily maintenance dose in the range of from about 10 mg to about 100 mg of carvedilol,

said first dosages each comprising carvedilol in an amount which is 10-30% of said daily maintenance dose,

said second dosages each comprising carvedilol in an amount which is 20-70% of said daily maintenance dose.

Art Unit: ***

2. The method of claim 1, wherein the daily maintenance dose is about 25 mg or about 50 mg.

3. The method of claim 1, further comprising administering to said patient at least one other therapeutic agent selected from the group consisting of angiotensin converting enzyme inhibitors, diuretics and cardiac glycosides.

- 4. The method of claim 3, wherein the angiotensin converting enzyme inhibitor is selected from the group consisting of captopril, lisinopril, fosinopril, enalspril and pharmaceutically acceptable salts of captopril, lisinopril, fosinopril and enalspril.
 - 5. The method of claim 3, wherein said diuretic is selected from the group consisting of hydrochlorothiazide, torasemide, furosemide, and pharmaceutically acceptable salts of hydrochlorothiazide, torasemide and furosemide.
 - 6. The method of claim 3, wherein said cardiac glycoside is selected from the group consisting of digoxin, β-methyldigoxin and digitoxin.
 - 7. (Amended) A method of decreasing <u>a risk of</u> mortality caused by congestive heart failure in a patient, said method comprising administering to said patient first dosages once or twice daily, for a period of from 7 to 28 days, said first dosages each comprising carvedilot in an amount of about 3.125 mg or 6.25 mg,

then administering to said patient second dosages once or twice daily,

for a period of from 7 to 28 days, said second dosages each comprising

carvedilol in an amount of about 12.5 mg, and

then administering to said patient maintenance third dosages once or twice daily, said third dosages each comprising carvedilol in an amount of about 25.0 mg or about 50.0 mg.

8. A method as recited in claim 7, wherein at least one of said first, second and maintenance dosages further comprises at least one other therapeutic agent selected from the group consisting of an angiotensin converting enzyme inhibitor, a diuretic and a cardiac glycoside.

Application/Control Number: 10/721,022 Page 4

Art Unit: ***

9. (Amended) A method of treating to decrease <u>a risk of</u> mortality resulting from congestive heart failure in a patient in need of such treatment, said method comprising administering to said patient carvedilol, alone or in combination with at least one other therapeutic agent, in unit dosages once or twice daily, for a period of from 7 to 28 days, said unit dosages each comprising a pharmaceutical formulation comprising carvedidol in an amount of about 3.125 mg or about 6.25 mg.

10. A method of treating congestive heart failure in a patient in need of such treatment, said method comprising: administering to said patient first dosages at least daily for a period of from 7 to 28 days, said first dosages each comprising carvedilol,

then administering to said patient second dosages at least daily for a period of from 7 to 28 days, said second dosages each comprising carvedilol, and

then administering to said patient third dosages daily for a maintenance period, said third dosages each comprising carvedilol, said third dosages each comprising a daily maintenance dose in the range of from about 10 mg to about 100 mg of carvedilol,

said first desages each comprising carvedilel in an amount which his 10-30% of said daily maintenance dose,

said second dosages each comprising carvedilol in an amount which is 20-70% of said daily maintenance dose.

11. Method of claim 10, wherein carvedilol is administered to the patient once or twice daily.

12. (New) A method according to claim 1, wherein the daily maintenance dose and the maintenance period have been shown to statistically decrease the risk of mortality caused by congestive heart failure.

Application/Control Number: 10/721,022 Page 5

Art Unit: ***

13. (New) A method according to claim 1, wherein said patient has class II-IV congestive heart failure.

- 14. (New) A method according to claim 7, wherein the maintenance third dosages are administered to decrease a risk of mortality caused by congestive heart failure, and for a maintenance period of greater than six months.
- 15. (New) A method according to claim 14, wherein the maintenance third dosages and the maintenance period have been shown to statistically decrease the risk of mortality caused by congestive heart failure.
- 16. (New) A method according to claim 7, wherein said patient has class II-IV congestive heart failure.

Art Unit: ***

Page 6

17. (New) A method according to claim 10, wherein the third dosages are administered to decrease a risk of mortality caused by congestive heart failure, and the maintenance period is greater than six months.

- 18. (New) A method according to claim 17, wherein the third dosages and the maintenance period have been shown to statistically decrease the risk of mortality caused by congestive heart failure.
- 19. (New) A method according to claim 10, wherein said patient has class II
 IV congestive heart failure.
 - 20. (Amended) A method of decreasing <u>a risk of</u> mortality caused by congestive heart failure in a patient, said method comprising administering to said patient first dosages once or twice daily, for a period of from 7 to 28 days, said first dosages each comprising carvedilol in an amount of about 3.125 mg,

then administering to said patient second dosages once or twice daily, for a period of from 7 to 28 days, said second dosages each comprising carvedilol in an amount of about 12.5 mg, and

then administering to said patient maintenance third dosages once or twice daily, said third dosages each comprising carvedilol in an amount of about 25.0 mg or about 50.0 mg.

Art Unit: ***

of about 6.25 mg.

21. (New) A method as recited in claim 20, further comprising, after administering the first dosages and before administering the second dosages, administering to said patient intermediate dosages once or twice daily, for a period of from 7 to 28 days, said intermediate dosages each comprising carvedilol in an amount

Page 7

- 22. (New) A method according to claim 20, wherein the maintenance third dosages are administered to decrease a risk of mortality caused by conquestive heart failure, and for a maintenance period of greater than six months.
- 23. (New) A method according to claim 22, wherein the maintenance third dosages and the maintenance period have been shown to statistically decrease the risk of mortality caused by congestive heart failure.
- 24. (New) A method according to claim 20, wherein said patient has class II
 IV congestive heart failure.
- 25. (New) A method as recited in claim 20, wherein at least one of said first, second and maintenance dosages further comprises at least one other therapeutic agent selected from the group consisting of an angiotensin converting enzyme inhibitor, a diuretic and a cardiac glycoside.

Art Unit: ***

Page 8

26. (New) A method of treating congestive heart failure in a patient in need of such treatment, said method comprising:

administering to said patient first dosages at least daily for a period of from 7 to 28 days, said first dosages each comprising carvedilol,

then administering to said patient second dosages at least daily for a period of from

7 to 28 days, said second dosages each comprising carvedilol, and

then administering to said patient third dosages daily for a maintenance period to

decrease a risk of mortality caused by congestive heart failure, said third

dosages each comprising carvedilol, said maintenance period is greater than six

months, and said third dosages each comprising a daily maintenance dose in the

range of from about 10 mg to about 100 mg of carvedilol.

Art Unit: ***

Page 9

said first dosages each comprising carvedilol in an amount which his 10-30% of said daily maintenance dose.

said second dosages each comprising carvedilol in an amount which is 20-70% of said daily maintenance dose.

- 27. (New) A method according to claim 26, wherein the third dosages are administered to decrease a risk of mortality caused by congestive heart failure, and the maintenance period is greater than six months.
- 28. (New) A method according to claim 27, wherein the third dosages and the maintenance period have been shown to statistically decrease the risk of mortality caused by congestive heart failure.
- 29. (New) A method according to claim 26, wherein said patient has class II
 IV congestive heart failure.
- 30. (New) Method of claim 26, wherein carvedilol is administered to the patient once or twice daily.